AUG 2 0 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 C.F.R. § 807.92.

The assigned 510(k) number is K012478

Summary Prepared on: 31 July 2001

Submitted by:

i-STAT Corporation
104 Windsor Center Drive
East Windsor, NJ 08520
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Contact:

Paul VanDerWerf, Ph.D., Vice President Regulatory Affairs and Quality Assurance

Establishment Registration Number: 2245578

Identification of the Device

Device Name:	i-STAT System (see Table 1 below)
Proprietary/Trade Name:	i-STAT System
Common Name:	Portable clinical analyzer
Classification Name:	See Table 1
Device Classification:	II
Regulation Number:	See Table 1
Panel:	Clinical Chemistry (75)
Product Code:	See Table 1

TABLE 1

Device Name	510(k) Number	Classification	Regulation	Product Code
Model 100 Portable Clinical Analyzer and Test Pack	K894914 K912387	Electrode, ion specific, sodium	21 C.F.R. § 862.1665	JGS
i-STAT Tests for Acid-Base Parameters;	K936081	Electrode measurement, blood-gases (pCO2, pO2) and blood pH	21 C.F.R. § 862.1120	CHL
i-STAT 200 Portable Clinical Analyzer	K940918	Electrode measurement, blood-gases (pCO2, pO2) and blood pH	21 C.F.R. § 862.1120	CHL
i-STAT Creatinine Test	K973292	Electrode, ion based, enzymatic, creatinine	21 C.F.R. § 862.1225	CGL
i-STAT Lactate Test	K982071	Acid, lactic, enzymatic method	21 C.F.R. § 862.1450	KHP
i-STAT Model 200 Portable Clinical Analyzer	K001154	Electrode, ion specific, sodium	21 C.F.R. § 862.1665	JGS
i-STAT Model 300 Portable Clinical Analyzer	K001387	Glucose oxidase, glucose	21 C.F.R. § 862.1345	CGA
i-STAT System	K011478	Acid, Lactic, Enzymatic Method	21 C.F.R. § 862.1450	KHP

Identification of the Predicate Device.

The predicate device is the i-STAT System (see Table 1 above).

Description of the Device.

The i-STAT System is used in conjunction with disposable i-STAT cartridges for determination of a variety of parameters in whole blood.

Intended Use of the Device.

The i-STAT PCA is used by trained medical professionals for running a variety of clinical chemistry tests and test panels contained in the i-STAT test cartridges.

Reason for Submission.

The software has been modified to diminish the interference on the PCO_2 test caused by the drugs thiopental sodium and propofol.

Conclusion.

These labeling changes do not affect prior substantial equivalence determinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 0 2001

Paul VanDerWerf, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
i-STAT Corporation
104 Windsor Center Drive
East Windsor, NJ 08520

Re: 510(k) Number: K012478
Trade/Device Name: i-STAT System
Regulation Numbers: 862.1120, 862.1145, 862.1170, 862.1225, 862.1345, 862.1600, 862.1665, 862.1770, 864.6400, 864.7140, 862.1450
Regulatory Class: II
Product Code: CHL, JGS, CDS, JPI, JBP, JFP, CGZ, CGL, CGA, CEM
Regulatory Class: I
Product Code: KHP
Dated: July 31, 2001
Received: August 2, 2001

Dear Dr. VanDerWerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K012478

Device Name: i-STAT System

Indications for Use:

The i-STAT System is used by trained medical professionals for running clinical chemistry tests for sodium, potassium, chloride, urea nitrogen, glucose, hematocrit, calcium, blood-gases (PCO_2, PO_2) and blood pH, creatinine, lactic acid, and activated whole blood clotting time in a variety of test panels contained in the i-STAT test cartridges.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012478

Rx

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)